

and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 20, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-R-211]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Type of Information Collection Request.** Reinstatement, with change of a previously approved collection for which approval has expired; **Title of Information Collection:** State Child Health Plan and Supporting Information Collection Requirements Referenced in Title XXI of the Social Security Act; **Form No.:** HCFA-R-211, OMB #0938-0707; **Use:** This revised Model template will enable states to apply for funds under Title XXI of the Social Security

Act, to initiate and expand the provision of child health insurance to uninsured, low income children in a effective and efficient manner that is coordinated with other sources of health coverage for children; **Affected Public:** State, Local or Tribal Government; **Number of Respondents:** 56; **Total Annual Responses:** 56; **Total Annual Hours:** 8,960.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 20, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Use of Long WAP Promoter in Mammary Tissue of Transgenic Animals

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: U.S. Patent Application Serial No. 07/943,246, filed September 10, 1992, entitled "Expression of Active Protein C in Mammary Tissue of Transgenic Animals Using a Long WAP Promoter" to the American Red Cross having a place of business in Rockville, Maryland. The patent rights in these inventions have been assigned to the United States of America.

The field of use will be the use of the invention for the production in transgenic animals of factor VIII, factor IX, fibrinogen, Protein C, and von Willebrand factor.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before June 26, 1998 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Leopold J. Luberecki, Jr., J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Box 13, Rockville, MD 20852-3804; Telephone: (301) 496-7735, ext. 223; Facsimile: (301) 402-0220. A signed Confidentiality Disclosure Agreement will be required to receive copies of the patent application.

**SUPPLEMENTARY INFORMATION:** The patent application claims a transgenic, non-human mammal containing an exogenous DNA sequence that has the 5' 4.2 kb promoter fragment of the mouse whey acid protein (WAP) gene, or a variant thereof, operably linked to a DNA sequence encoding an active polypeptide and a signal peptide, such that the WAP promoter is specifically active in mammary cells and the signal peptide is effective in directing the secretion of the polypeptide into the milk of the transgenic animal. The invention goes on to describe a process for the production of the polypeptide by using the promoter and the signal peptide to produce the desired polypeptide in the milk of the transgenic animal, collecting the milk, and isolating the polypeptide therefrom.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.